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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,293	08/24/2001	Emad S. Alnemri	480140.465	2539

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,293	ALNEMRI, EMAD S.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-31,36-39 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-31,36-39 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/24/04 has been entered.

Accordingly, claims 28-31, 36-39, 44-47, BIR1/BIR2 domains are being examined.

The submission of the Declaration by Dr. E. S. Alnemri is acknowledged and entered.

The following are the remaining rejections.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The reference of the supplemental information disclosure submitted on 02/04/04 has been reviewed, and the signed PTO-1449 of said supplemental information disclosure is enclosed hereto.

OBJECTION

1. Claims 44-47 are objected to because claim 44 is confusing. It is not clear that the claimed peptide or polypeptide consists of how many separate blocks of contiguous amino acids from residues 56-239 of SEQ ID NO:19, wherein these blocks of contiguous amino acids are less than 184 contigous amino acids.

2. The specification is objected to because the seemingly typographic error, SEQ ID NO:1, which should be SEQ ID NO:19, has not been corrected.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER

Claims 36-39, 44-47 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of a peptide or polypeptide comprising specific "residues 60-62" has no clear support in the specification and the claims as originally filed.

Applicant asserts that the claims have support in the specification, including page 17, line 18 through page 18, line 2.

A review of the specification discloses support for a peptide or polypeptide comprising at least 2 contiguous amino acids from residues 56-139 of SEQ ID NO:19, or at least 2 to 185 contiguous amino acids of SEQ ID NO:19. (It is noted that the typographic error SEQ ID NO:1 referred in the specification should have been corrected to SEQ ID NO:19).

The subject matter claimed in claims 36-39, 44-47 broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 36-39, 44-47 pertaining to while being enabled for an isolated fragment of the Smac polypeptide of SEQ ID NO:19, wherein said fragment consists of less than 184 contiguous amino acid residues from residues 56-239 of SEQ ID NO:19, wherein said fragment comprises at least seven contiguous amino acids from at least residues 56-85 of SEQ ID NO:19, and wherein said fragment is capable of specifically bind to the BIR1/BIR2 domain of the inhibitor of apoptosis protein XIAP, but is not enabled for an isolated Smac peptide or polypeptide comprising or consisting of at least seven contiguous amino acids from at least residues 56-85 of SEQ ID NO:19, wherein said peptide or polypeptide comprises residues 60-62 of SEQ ID NO:19, wherein said peptide or polypeptide comprises or consists of less than 184 contiguous amino acid residues from residues 56-239 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically bind to at least a portion of an inhibitor of Apoptosis protein, for remains for reasons already of record in paper No.16 of 11/04/03.

Claims 28-31 are rejected to the same reasons.

Applicant asserts that the amendment of claims 36 and 44 would obviate the rejection.

Applicant argues that not all seven amino acids 56-62 are required for binding to the BIR1/BIR2 domain, since binding to the BIR1/BIR2 domain still occur in the absence of residues 56-69, as shown for N-terminal mutant 4, and C-terminal mutants N7, N30

and N39, in figure 10, indicating that residues 60-62 are important for binding to the BIR1/BIR2 domain. Applicant argues that it is routine to screen for the claimed peptide or polypeptide for the ability to bind to the BIR1/BIR2 domain.

Applicant's arguments set forth in paper of 02/24/03 have been considered but are not deemed to be persuasive for the following reasons:

Due to the language "comprise", claims 28-31 encompass unknown sequences attached to at least residues 56-85 of SEQ ID NO:19, which is less than 184 contiguous amino acid residues from residues 56-239 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically binding to at least a portion of an inhibitor of Apoptosis protein.

Due to the language "comprise", claims 36-39 encompass unknown sequences attached to at least seven contiguous amino acids from at least residues 56-85 of SEQ ID NO:19, which is less than 184 contiguous amino acid residues from residues 56-239 of SEQ ID NO:19, wherein said peptide or polypeptide comprises residues 60-62 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically binding to at least a portion of an inhibitor of Apoptosis protein.

Further, although claim 44 recites the language "consisting of", however, due to the language "at least", there is no limitation concerning the size of the amino acid sequence that the claimed peptide or polypeptide consists of. Therefore claims 44-47 encompass a polypeptide consisting of an amino acid sequence of any length and any structure or composition, provided it contains at least seven contiguous amino acids from at least residues 56-85 of SEQ ID NO:19, which is or consists of less than 184

contiguous amino acid residues from residues 56-239 of SEQ ID NO:19, wherein said peptide or polypeptide comprises residues 60-62 of SEQ ID NO:19, and wherein said peptide or polypeptide is capable of specifically binding to at least a portion of an inhibitor of Apoptosis protein.

Applicant has not taught how to make the claimed peptide or polypeptide such that it still retain the ability to bind to the BIR1/BIR2 domain.

Although the seven amino acids 56-62 of SEQ ID NO:1 (or N7) by itself is capable of binding to the BIR1/BIR2 domain, and although the presence of amino acids 60-62 in the mutant 4, N7, N30 or N39 (see figure 7) seem to be required for binding to the BIR1/BIR2 domain, one cannot predict that any amino acid sequence of any structure attached to a sequence having at least 7 amino acids of amino acids 56-85 of SEQ ID NO:1, comprising amino acids 60-62 of SEQ ID NO:1 would have the conformation necessary to fit into the BIR1/BIR2 domain for binding to said domain. It is well known in the art that a conformation of a polypeptide depends on the amino acid composition, wherein interaction between different amino acids could have a significant influence on the conformation of said polypeptide. For example, Queen et al, US 5530101, teach that characteristics such as interactions from amino acids in the CDRs and the framework region could contribute to the conformation of the CDRs of an antibody, i.e. prevention of distortion of CDRs. Bowie et al (Science, 1990, 247: 1306-1310, especially columns 1-2, p.1306) teach that the ability of proteins to fold into unique three-dimensional structures depends on the amino acid composition of the protein, and that certain positions in the sequence are critical to the three dimensional

structure/function relationship. Thus, based on the teaching in the art, it is expected that the amino acids that are attached to the seven amino acids of residues 56-85 of SEQ ID NO:19 could have important influence in shaping the conformation of the polypeptides comprising the seven amino acids of residues 56-85 of SEQ ID NO:19, wherein said conformation is of significant importance for fitting into and binding to the BIR1/BIR2 domain.

The specification has not taught what the structure is for the sequences attached to the seven amino acids of residues 56-85 of SEQ ID NO:19. The specification has not taught what the conformation of the claimed numerous polypeptides is such that they would fit into and bind the BIR1/BIR2 domain.

Based on the teaching in the art and in the specification, one cannot predict that additional sequences, with unknown structure, attached to the seven amino acids of residues 56-85 of SEQ ID NO:19 would not change the conformation and structure and thus the binding properties of the seven amino acids of residues 56-85 of SEQ ID NO:19, comprising residues 60-62 of SEQ ID NO:19, in such an unpredictable way, that one cannot screen for binding to the BIR1/BIR2 domain without undue experimentation.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CHRISTINA CHAN can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

June 02, 2004